

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Duft, et al.

Serial No.: 08/870,762

Filed: June 6, 1997

Title: METHODS FOR TREATING OBESITY

Group Art Unit: 1645

Examiner: S. Devi

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DECLARATION UNDER 37 C.F.R. § 1.131

Honorable Commissioner of  
Patents and Trademarks  
Washington, D.C. 20231

Dear Sir:

1. Having reviewed the May 30, 2002 Office Action in the above-captioned case, we understand that pending claims 1-14 in the subject patent application have been rejected by the U.S. Patent and Trademark Office ("PTO") for alleged lack of novelty in view of an Abstract bearing the date "May 1997" (Thompson *et al.*, *Diabetes*, 46(Supp. 1):30A). A copy of this document, which was included in an Abstract Book for the 57<sup>th</sup> Scientific Sessions of the American Diabetes Association (the "ADA," publisher of *Diabetes*) in Boston, MA on June 21-24, 1997, is attached hereto as Exhibit A and is hereinafter referred to as the

"Thompson/Pearson/Schoenfeld/Kolterman Abstract."

2. The Thompson/Pearson/Schoenfeld/Kolterman Abstract describes clinical experiments undertaken by Amylin Pharmaceuticals. All of the named authors, Robert Thompson, LeeAnne Pearson, and Steven Schoenfeld, as well as Dr. Kolterman, were employees of Amylin Pharmaceuticals, Inc. at the time the experiments described therein were planned and

carried out, prior to its publication, including experiments designed and supervised by Dr. Kolterman relating to weight loss.

3. Assuming for the purposes of this Declaration the assertion of the Patent Office that claims 1-14 of the present application first filed on June 6, 1997 were anticipated by the Thompson/Pearson/Schoenfeld/Kolterman Abstract, we thus note that the information referenced in the Thompson/Pearson/Schoenfeld/Kolterman Abstract relates to work done under the direction and supervision of one of the undersigned co-inventors, Dr. Orville Kolterman at Amylin Pharmaceuticals, who is also its co-author.

4. Attached Exhibits B, C, and D demonstrate, furthermore, that the subject matter of the Thompson/Pearson/Schoenfeld/Kolterman Abstract relied on by the PTO was based on a reduction to practice of the subject matter thereof not later than January 6, 1997.

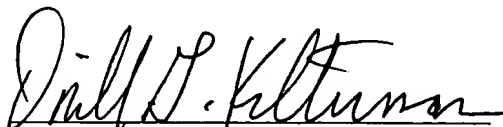
5. A copy of the Abstract Preparation Guidelines governing submission of this Abstract to the ADA for the 57<sup>th</sup> Scientific Sessions is attached hereto as Exhibit B, showing that the Thompson/Pearson/Schoenfeld/Kolterman Abstract was prepared prior to January 6, 1997, and submitted to the ADA on or before January 6, 1997, for the 57<sup>th</sup> Scientific Sessions in Boston, MA on June 21-24, 1997. As evidenced by Exhibit B, the ADA required that abstracts be received by January 6, 1997 in order to be published in the Abstract Book for the 57<sup>th</sup> Annual Meeting. Paragraph 33 in the Exhibit B Abstract Preparation Guidelines specified that any abstracts submitted after January 6, 1997 were deemed "late-breaking research" abstracts that would "not be published in the Abstract Book" nor "appear in the Final Program because of printing deadlines." As specified in Paragraph 7 of Exhibit B, the ADA did not permit changes to submitted Abstracts.

6. Attached as Exhibit C is a copy of the Abstract Submission form that accompanied the Thompson/Pearson/Schoenfeld/Kolterman Abstract submitted to and received by the ADA on or before January 6, 1997. As evidenced by Exhibit C, the Thompson/Pearson/Schoenfeld/Kolterman Abstract was not submitted as a "late-breaking research" abstract. Thus, in accordance with the Exhibit B Abstract Preparation Guidelines, it was included in the May 1997 *Diabetes* Abstract Book cited by the PTO. Further, the content of Abstract submitted to the ADA (Exhibit C) is the same as the published Abstract bearing the date "May 1997" (Thompson *et al.*, *Diabetes*, 46(Supp. 1):30A) (Exhibit A).

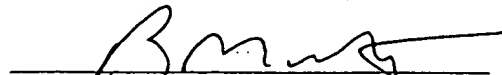
7. Attached as Exhibit D is a letter of acceptance from the ADA to Robert Thompson dated March 17, 1997, establishing that the Abstract submitted to and received by the ADA on or before January 6, 1997 was reviewed and accepted for publication not later March 17, 1997.

We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 101 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above-identified U.S. Patent Application or any Patent issued thereon.

Dated: November 27, 2002

  
Orville G. Kolterman, M.D.

Dated: ~~November~~ December 2, 2002

  
Bradford J. Duft